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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,958	12/26/2001	Dan L. Eaton	P3030R1C7	4529

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EXAMINER

KOLKER, DANIEL E

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,958	EATON ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,26-29 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-29,32,43 and 44 is/are allowed.
- 6) ☒ Claim(s) 22,26 and 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's remarks and amendments filed 1 July 2005 have been entered. Claims 23 – 25 and 30 – 31 have been cancelled, and claims 35 – 44 have been added. Claims 22, 26 – 29, and 32 – 44 are pending and under examination.
2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The correction of inventorship under 37 CFR 1.48(b) is accepted.

Information Disclosure Statement

5. The information disclosure statement filed 1 July 2005 has been considered. The BLAST results indicate that applicants are aware of nucleic acids and proteins with identity or homology to the one claimed herein. However the results cannot be considered because there is no alignment provided, nor is there an indication of the percent identity between the claimed sequence and the reference sequences. Applicant states on pp. 7 – 8 of the remarks that the newly-submitted documents include references to the publication dates of the sequences. Applicant is advised that the BLAST results submitted appear to be a list of sequences which match, but do not provide either alignments or indications of how the sequences are related to the instantly-claimed peptides. Therefore the examiner cannot determine if the sequence accession numbers submitted by applicant constitute prior art. Furthermore the search results submitted appear to be the results are not publicly available documents. Applicant is directed to MPEP 609 and 37 CFR 1.97 and 1.98.

Withdrawn Objections and Rejections

6. The following objections or rejections made in the previous office action are withdrawn:
The objections to the specification. Applicant has deleted the hyperlinks and changed the title.

The rejections under 35 USC 112, first paragraph, for lacking enablement due to failure to meet the requirements for biological deposit. Applicant's declaration filed 1 July 2005 is sufficient to overcome the rejection

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The rejections under 35 USC 112, second paragraph. Applicant has canceled language that was the basis of these rejections.

The rejections under 35 USC 102. Applicant's arguments that Lal does not teach a sequence 98% identical is persuasive. Applicant has canceled claims to polypeptides less than 98% identical to SEQ ID NO:61, obviating the rejections over WO 99/312316 and WO 99/53051.

Maintained Objections and Rejections

Priority

7. The effective priority date of the instant application is considered to be the filing date of the international application PCT/US00/05601, filed 1 March 2000 for the reasons made of record in the previous office action. Applicant did not traverse this statement.

Objections and Rejections Necessitated by Amendment

Claim Rejections - 35 USC §§ 102 and 103

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 22, 26, 33, and 35 – 41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either Tang et al. (US Patent Application Publication 2003/0232054, published 18 December 2003, filed 8 November 2002, claiming priority to application 09/491404, filed 25 January 2000) or Tang et al. (WO 01/55437, published 2 August 2001, filed 25 January 2001, claiming priority to 09/491404, filed 25 January 2000).

Tang et al. (both publications) teach SEQ ID NO:245, which is a polypeptide sequence 99.7% identical to applicant's SEQ ID NO:61. The only difference between the prior art sequence and applicant's SEQ ID NO:61 is a single amino acid substitution at residue 125. Tang (2001) teaches that SEQ ID NO:9, which is a nucleic acid sequence, encodes SEQ ID NO:245, and that the nucleic acid sequence appeared as SEQ ID NO:1525 in 09/491404 (see table 6, entry for SEQ ID NO:9). 09/491404 discloses this nucleic acid sequence, and also discloses that proteins encoded by the nucleic acid sequences of the application are part of the invention (see pp. 18 – 19 of the '404 application). Furthermore, the '404 application discloses the first 45 amino acids of the protein encoded by SEQ ID NO:1525 (see Table 2, entry for SEQ ID NO:1525). These residues are 100% identical to the first 45 residues of applicant's SEQ ID NO:61. While the '404 application does not disclose the entire sequence of the polypeptide, Tang et al. were clearly in possession of the isolated polypeptide, as a compound and its properties are inseparable. Thus the teachings of Tang (both publications) clearly meet the percentage identity requirements of claims 22, 26, 35 and 38. Tang is silent as to whether the polypeptide has the ability to induce mesangial cell proliferation or to induce fetal hemoglobin; these properties are explicitly recited in claims 22 and 26. Rejections under 102/103 are proper when the prior art discloses a product that seems to be identical except that the prior art is silent as to an inherent property (see MPEP 2112 (III)).

Claims 33 and 41 are drawn to fusion proteins comprising the claimed sequences. Tang teaches such proteins (see p. 32 line 33 – p. 34 line 5 of Tang 2001 for example), and thus the claims are rejected. Claims 36 and 39 are drawn to the proteins without their signal peptides. Tang teaches how to identify the signal sequence (see p. 43, paragraph 0441 of Tang 2003 and p. 19, lines 9 – 26 of the '404 application), and disclosed the signal sequence in the '404.

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application and explicitly disclosed that proteins lacking their associated signal sequences are part of the invention (see p. 13, paragraph [0117] of Tang 2003 or p. 28 lines 18 – 26 of Tang 2001 for example). Thus the prior art contemplates the protein without the signal sequence, teaches the artisan how to make the proteins without their signal sequences and discloses the signal sequence of the protein. Claims 37 and 40 are drawn to polypeptides encoded by the sequence of ATCC 203971 but this is a product-by-process limitation and since the prior art references disclose the product these claims are rejected as well.

10. Claims 22, 26, and 33 – 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang (US Patent Application Publication 2003/0232054) in view of Lo et al. (1998. Protein Engineering 11:495-500) or in the alternative over Tang (WO 01/55437) in view of Lo. The reasons why Tang (both publications) is deemed to meet the limitations of claims 22, 26, 33, and 35 – 41 are presented in the previous paragraphs. Neither Tang publication teaches polypeptides fused to immunoglobulin Fc region.

Lo et al. teach fusing a nucleic acid sequence encoding essentially any mammalian protein can be fused to immunoglobulin Fc region (p. 495, paragraph spanning the two columns). Lo et al. also teach this is advantageous as it allows rapid production and purification of gene products, which is necessary to identify and understand their functions (p. 495, second paragraph). Furthermore Lo et al. teach that their method is particularly useful as it allows for increased quantities of the proteins, with the advantage that they are secreted in the culture medium (p. 499, Discussion, first paragraph), allowing easy recovery. It would have been obvious to one of ordinary skill in the art to create a fusion protein comprised of the aforementioned proteins from Tang and Fc, with a reasonable expectation of success. The motivation would be to rapidly produce the protein at high purity, as taught by Lo et al.

Conclusion

11. Claims 22, 26, 33 – 42 are rejected.
12. Claims 27 – 29, 32, and 43 - 44 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHARON TURNER, PH.D.
PRIMARY EXAMINER

9-20-05

Daniel E. Kolker, Ph.D.

September 19, 2005